DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 31, 2014

Stryker Spine
Garry Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K142699
Trade/Device Name: LITe® Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 2, 2014
Received: October 6, 2014

Dear Dr. Hayeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142699

Device Name
LITe(R) Plate System

Indications for Use *(Describe)*

The LITe® Plate System Universal, Sacral, 2 Screw and 4 Screw Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); Pseudoarthrosis; Spondylolysis; Spondylolisthesis; Spinal stenosis; Tumors; Trauma (i.e. Fractures or Dislocation); Deformities (i.e. Scoliosis, Kyphosis or Lordosis); Failed Previous Fusion

The LITe® Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: LITe® Plate System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Garry T. Hayeck, Ph.D. Senior Regulatory Affairs Specialist Phone: 201-760-8043 Fax: 201-962-4043 E-mail: garry.hayeck@stryker.com
Date Prepared	December 31, 2014
Trade Name	LITe® Plate System
Common Name	Appliance, fixation, spinal intervertebral body
Proposed Class	Class II
Classification Name and Number	Spinal intervertebral body fixation orthosis 21 CFR §888.3060
Product Code	KWQ
Predicate Devices	**Primary Predicate:** Stryker Spine, CENTAUR™ Spinal System, K001844 **Additional Predicates:** **Universal, Sacral, 2 Screw, and 4 Screw Plates** • Stryker Spine, CENTAUR™ Spinal System, K994347 • Medtronic, PYRAMID® +4 Anterior Lumbar Plate System, K080429 • NuVasive, Lateral Plate System, K091071 • Spinal USA, Anterior Lumbar Plate System, K091044 • Globus Medical, CITADEL™ Anterior Lumbar Plate System, K062836 • Stryker Spine, THOR Anterior Lumbar Plate, K080773 **Buttress Plate** • Spinal USA, RCS Anterior Buttress Plate, K092659 • Spinal USA, Anterior Lumbar Plate System, K091044 • Stryker Spine, THOR Anterior Lumbar Plate, K080773
Device Description	The LITe® Plate System is an anterior/anterolateral/lateral plate system that may be used in the thoracic, lumbar, and sacral spine (T1-S1). The LITe® Plate System consists of plates and screws manufactured from titanium alloy (Ti6Al4V) per ASTM F136 and ISO 5832-3, as well as associated manual general surgical instrumentation. The implants are available in a variety of sizes to accommodate various patient anatomies.
Intended Use	The LITe® Plate System Universal, Sacral, 2 Screw and 4 Screw Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);

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	• Pseudoarthrosis; • Spondylolysis; • Spondylolisthesis; • Spinal stenosis; • Tumors; • Trauma (i.e. Fractures or Dislocation) • Deformities (i.e. Scoliosis, Kyphosis or Lordosis) • Failed Previous Fusion The LITe® Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.
Summary of the Technological Characteristics	As established in this submission, the LITe® Plate System was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including intended use, material composition, principles of operation and design.
Summary of the Performance Data	Nonclinical testing was performed to demonstrate that the LITe® Plate System is substantially equivalent to its predicate devices. The following testing and analysis was performed: • Static and dynamic compression testing per ASTM F1717-14 • Static torsion testing per ASTM F1717-14 • Buttress plate expulsion testing
Conclusions	The LITe® Plate System has identical indications, technological characteristics, and principles of operation as its predicates. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicates. The LITe® Plate System was shown to be substantially equivalent to its predicate devices.